Health Information Technology Standards Committee
DRAFT
Summary of the July 19, 2012 Meeting

KEY TOPICS

1. Call to Order and Opening of the Meeting

Mary Jo Deering, Office of the National Coordinator (ONC), welcomed participants to the meeting of the HIT Standards Committee (HITSC). She reminded participants that it was a Federal Advisory Committee (FACA) meeting, with an opportunity for the public to make comments, and that a transcript of the meeting would be available on the ONC Website.

2. Opening Remarks

Jodi Daniel, Director, Office of Policy and Planning, ONC, remarked that nominations for the HITSC and the HITPC closed on June 11. ONC received "many" applications indicating great interest in HIT. Staff is reviewing the applications from the perspective of maintaining fair, balanced and committed advisory groups. The Governance RFI comment period closed June 29. 140 comments were received on the more that 60 questions.

3. Review of the Agenda

John Halamka, Vice Chairperson, conducted the meeting in the absence of the chairperson. He asked members about amendments or comments to the summary of the June 20, 2012 meeting. Hearing none, he declared the summary approved.

Action item #1: The summary of the June 2012 meeting was declared approved.

He recognized each of the agenda items, noting in particular the contributions of Dixie Baker. The work of the NwHIN Power Team constitutes an update of the HITSP work on standards readiness. He reported tha**t** James Ferguson had informed him prior to the meeting that the Federal Drug Administration had recently issued a Notice of Proposed Rule Making (NPRM) on standards for devise manufactures on which the HITSC should comment. Halamka asked Deering to arrange for the topic to be assigned to a workgroup. He said that Leslie Kelly Hall had talked to him about the developing terminologies for patient engagement not being in SNOMED and the National Library of Medicine repository.

4. NwHIN Power Team: Initial Report on Criteria to Assess Maturity of Standards and Specifications

Dixie Baker, Chair, showed slides and presented preliminary evaluation criteria. These criteria, attributes and the accompanying metrics will be used to evaluate the readiness of standards for adoption and implementation. Baker reviewed slides on criteria:

Maturity Criteria:

- Maturity of Specification
- Maturity of Underlying Technology Components
- Market Adoption

Adoptability Criteria:

- Ease of Implementation and Deployment
- Ease of Operations
- Intellectual Property

She went on to show attributes for each criterion and for each attribute metrics for high, medium and low. She invited interested persons to the next team meeting on July 26, 2012, at which ONC staff will present on RESTful Exchange specification development and the team will begin an evaluation exercise using HL7 Context-Aware Knowledge Retrieval ("InfoButton").

Q and A

Halamka commented that S&I Framework was built on mature standards. Query Health needed refined standards. And transition of care required new standards, all of which show how the team's framework can be used to evaluate standards.

Kelly Hall talked about the natural tension between innovation and use of mature standards. She asked about a criterion for innovation. There is a new role for patients and families. Work is needed to accommodate innovation as well as the use of existing standards for patients. Baker responded that team members intend these recommendations to inform, not to dictate absolutes. The approach is a disciplined way to evaluate standards; it is not a scoring system. Some but not all standards will be codified in law.

David McCallie, team member, acknowledged that the process is qualitative. As new standards emerge, these criteria will help to make good standards.

Jim Walker noted the need to distinguish between experimentation and requirement. Halamka said the evaluation approach is a classification scheme, not a pass-fail system.

Wes Rishel talked at length about the model or paradigm, acknowledging that he would be hard pressed to think of a functional standard adopted without problems with maturity. Standard means specified in sufficient detail so that two organizations with the same specifications are interoperable. Most functional standards were flawed in their past execution. Having a level of confidence before rolling out to the public is important. He emphasized the importance of a standard's continuity with its prior operability. For example, the Consolidated CDA does not consist of a lot that is new; it is a fix and a rearrangement. And one can be more comfortable with it than with a totally new standard. The HITSC must urge ONC to recognize the need for a feedback loop faster than the current two-year period. Guidance for technical specification is needed. Baker acknowledged the need to capture in the approach both continuity with prior versions and experience with early adoption. Rishel went on to speak about recognizing the recommendation of the best available standard for transition of care although there is no experience with implementation of the standard. The standard does have continuity with prior versions. To raise the bar on meaningful use, ONC had to get ahead of standards.

Chris Shute remarked on his puzzlement by the burden of optionality on the receiver. Optionality is nearly always undesirable: When would it be good? McCallie responded that not all optionality is equal. A standard that can grow is good. (He gave an example.) But the burden is that the receiver can get content it cannot handle.

Ferguson inquired about implementation independence and coordination across actors. Baker indicated the point is that when coordination is required, it can bog down implementation. Ferguson argued for greater precision, saying that he had in mind both use cases for which the criteria are applicable and cases for which coordination should be improved, such as integration of clinical decision support across organizations or device interoperability. The criterion may be contrary to what is required for health care reform. Baker asked him to submit language to capture his concept.

Walker observed that the operational definitions are brilliant. The theme is limiting what can be required of industry. The approach protects industry from burdens.

Daniels wondered about the application of the model: How would it work if more than one standard was under consideration? What about the interaction of multiple standards? Baker related that the process described to the team would be one in which ONC determines a need and then asks the team to evaluate the readiness of that standard to become a national standard. Availability of alternatives is not currently included in the model. Baker indicated that she would bring it up for consideration. She reported that the team did not consider a situation in which ONC asked which of two or more standards is better.

Floyd Eisenberg commented that the model is valuable for persons working to develop standards. It would also be useful to know about maintenance of the standard.

Arien Malec observed that optionality has both benefits and disadvantages.

Rishel spoke about optionality, referring to his work on HL7. He said that optionality generally results from a standards committee having failed to take all use cases into account. He cited lab certification and public health reporting in stage 1 as an example. The problem was fixed for stage 2. The environment is such that partners have varying stages of technology. They must make decisions based on business interests not compatibility of their technology. He approved of the transition of care approach for 2014 in which a provider must send certain elements in CDA format and must be able to receive certain elements without regard to format. This sets a minimum standard for interoperability. He disagreed with Ferguson's comment about industry definitions of interoperability. He announced that he wished to see a better definition.

Walker reminded the members that they had had this discussion many times. He noted that no facts had been presented during the discussion. He wondered about the existence of a discipline that studies optionality. No nominations were heard.

Walter Suarez observed that the evaluation model does not use the source of the standard. He indicated that ANSI evaluates the source along with other attributes. He suggested the addition of source. He also suggested taking into account the practical applicability of a standard. He wondered about the use of the model for stage 3 and in the S&I Framework. Doug Fridsma, ONC, said that the evaluation model will help to show areas in which S&I activity is needed. It can guide the placement of resources, contribute to HITSC consistency and increase its credibility.

Halamka said that the model will be a guide for evaluation, using context and purpose. He suggested using RESTful as developed by MITRE for a test, apparently having missed Baker's description of the proposed test. She asked him whether he was asking for a test of RESTful instead of Info Button, which she explained is smaller and more digestible. Halamka told her to proceed with Info Button.

5. Report on Hearing on Trusted ID for Providers in Cyberspace

Dixie Baker, Chair, Privacy and Security Workgroup, spoke about the hearing, which was co-hosted by the Privacy and Security Tiger Team. The hearing focused exclusively on identify proofing and authentication for providers across organizations. Authorization was not included. She reported that since the first HITPC hearing on this topic, important policy developments had occurred, stimulating the development of the following market-based identity solutions:

- National Strategy for Trusted Identity in Cyberspace (NSTIC) – released by the White House in April 2011
- Update to NIST Special Publication 800-63, Electronic Authentication Guideline (December 2011)

Baker described NIST 800-63-1 Level of Assurance (LOA) 3:

- LOA 3 requires the use of at least two factors for remote-access authentication
- Identity proofing (assurance of the identity of an individual at time of registration & issuance of authenticator)
    - Verification of identifying materials and information (including government-issued picture ID)
- Authentication (proof that the individual is who she claims to be at time of attempted access)
    - At least two factors, typically a key encrypted under a password (not required to be implemented in hardware)
    - Must resist eavesdroppers
    - May be vulnerable to man-in-the-middle attacks (e.g., phishing and decoy websites), but must not divulge authentication key

Banker showed a slide that listed the panelists and their primary affiliations. Although invited, the Drug Enforcement Administration (DEA) did not send a representation, which was unfortunate, according to Baker. She presented the workgroup members' collective observations:

- No established or de facto standard exists for either ID-proofing or authenticating providers
    - Current state-of-practice is passwords (LOA 2)
    - 5 of top 6 vectors of attack in 2011 data breaches were tied to passwords (health sector #1 target in 2011)
- Focus of identity assurance in healthcare seems to be shifting from the entity/organization level to the individual level – most of the testimony presented focused on the latter but may be a participant bias
    - However, neither Exchange nor Direct requires identity assurance at LOA 3
    - No recommendation for LOA 3 was included in recommendations for Stage 2 meaningful use
- NIST 800-63-1 LOA 3 authentication is feasible, and consistent with the direction the industry is heading
    - Mobile technologies have emerged as key platform for LOA 3 two-factor solutions
- The need for a high level of assured identity extends to every other health care provider (nurses, pharmacists, dentists, therapists, etc), and even to administrative staff
- Important to assure that policies and approaches used for assuring the identity of individuals who access health information within an organization are compatible with the need for a high level of assurance of the identity of providers who access and exchange health information with other providers external to the organization
- Both government and private industry are embracing the Federal Identity, Credential, and Access Management (FICAM) Trust Framework and NIST SP 800-63-1
    - Secure, interoperable and privacy-enhancing process by which federal agencies and private sector can leverage commercially issued digital identities and credentials
    - Four non-federal organizations have been approved to be Trust Framework Providers (TFPs) – who then assess and accredit commercial identity providers who conform to the USG profiles and abide by the privacy criteria
        - Kantara -InCommon -SAFE Bio-Pharma -Open Identity Exchange (OIX)
    - CMS has identified risks that warrant LOA 3 assurances and will use FICAM-certified credential providers to meet this need
- Support and momentum for the NSTIC initiative is building – expect NSTIC to emerge as the common basis for identity management for both the private and public sectors
    - Calls for Identity Ecosystem – "an online environment where individuals and organizations will be able to trust each other because they follow agreed upon standards to obtain and authenticate their digital identities"
    - Emphasis on authenticating identity without disclosing private information will be appreciated by both the healthcare industry and by consumers
    - Not clear what will cost – business models still emerging

    - Commercial marketplace is developing solutions based upon NSTIC principles and 800-63-1

- e.g., DrFirst, OneID, Verizon authentication solutions all meet LOA 3 requirements and are consistent with NSTIC principles

She summarized:

- Momentum toward highly assured identity is building, as several critical forces are aligning:

1. Increasing awareness of vulnerabilities and workflow impacts associated with use of passwords
2. Rapidly dropping cost of digital certificates – from 2-or-3-digit pricing per certificate just 5 years ago to less than $1 to "free" today – resulting in broader adoption in all sectors
3. DEA is requiring a high (>LOA 3) for all prescribers of controlled substances
4. VA is using high (>LOA 3) with all of their internal providers, and looking at how to expand to external providers
5. CMS plans to move "as early as next year" to requiring ALL of its contracted providers to use high LOA identity proofing and authentication when conducting business with Medicare

- Current HIE state-of-practice still relies on passwords – need for a roadmap for progressing toward LOA 3

In conclusion, she asked members to send her their opinions on L0A 3.

Q and A

Halamka asked about a password and a one-time code used on a cell phone meeting LOA 3 standards. Baker replied that they would meet LOA 3 standards because the two required authenticators are used. He asked about adaptive authentication when the user logs on in a new or atypical location and in addition to username and password must respond to questions. Baker explained again about two authenticators for LOA 3.

Arien Malec expressed worry about NSTIC applicability to health care, particularly regarding proxy roles. Physician signature is required on claims. Authentication of individuals without recognition of proxies would be a problem. Multiple provider practices often use a referral manager. Also, the continuing need for business-to-business transactions makes the NSTIC approach difficult. He was worried about the applications of NSTIC that are hard wired for government as well. He described a situation in the operating room with multiple actors and 3-second password timeouts that would be dangerous for patients. He went on. Sometimes machine-to-machine transactions may involve a person on each end and not neatly fit into NSTIC. Baker reminded him of the focus on the hearing—organization to organization exchange, indicating that his comments, while important, were not necessarily relevant to the hearing observations.

Another member referred to the changing focus from entity to individual authentication, saying that HIPAA binds to organizations. Much communication is from entity to entity. Entities should be able to manage the roles of individuals within their organizations. Baker corrected him to say that HIPAA makes individuals responsible as well. Again, she referred to the stated focus of the hearing—organization to organization communication. Both policy and capability are involved. Daniels confirmed that individuals can be held accountable in specific circumstances under HIPAA. The other member went on to describe situations in exchange when the individual is unknown. Organizations have to manage the roles of individuals under their authority.

Noting that the discussion was off schedule, Halamka optimistically called for lightening comments.

Marc Overhage spoke about the capability to authenticate and to take action anonymously, saying that the latter must be prevented. He opined that the proposed model would require that actors be known. He went on to talk about the importance of knowing the individual's role in an organization. Once again, Baker reminded a member about the scope of the hearing. Role pertains to authorization, which was out of the hearing's scope. She informed him that operating systems separate authentication and assigned role. Halamka referred to the value of brevity.

McCallie opined that health care needs a specific definition of level. The NIST definition is not completely applicable to health care. There is a distinction between LOA 3 and two-factor authentication. The issue with NSTIC is its incompatibility with the health business case, for example, the charges for transactions.

Walker observed that anonymity can be useful, for example, in responding to surveys and reporting safety violations. Rishel asked, "What is the ask?" What will the HITSC do with this information? When individual authentication is preferred over entity authentication has yet to be discussed. Halamka reminded the members that the presentation was for informational purposes only. Baker announced that she will report on the hearing to the HITPC.

6. Updates from ONC

Carol Bean, Director, Office of Certification, showed slides and talked about the transition from a temporary to a permanent certification program. She reported that a few days ago ANSI accredited the following HIT certification bodies:

- Certification Commission for Health Information Technology (CCHIT)
- Drummond Group, Inc.
- ICSA Laboratories, Inc.
- InfoGard Laboratories, Inc.
- Orion Register, Inc.

These certification bodies must now be authorized by ONC. The authorization process will be a swift one. Also, the National Voluntary Laboratory Accreditation Program (NVLAP), approved by regulation as the Accreditation Body for Test Labs in the Permanent Certification Program, accredited these test labs:

- Certification Commission for Health Information Technology (CCHIT)
- Drummond Group, Inc.
- ICSA Laboratories, Inc.
- InfoGard Laboratories, Inc.
- SLI Global Solutions

Bean went on to describe unit-based testing and scenario-based testing. Testing methods are sub-regulatory. When the stage 2 final rule is published, more information will be available. There are 818 EHR vendors and developers and 1848 unique products. Hybrid certification was recently instituted to allow all products certified to meet the inpatient criteria to satisfy all of the ambulatory criteria. The certification website is being rebuilt.

Q and A

Bean clarified that applications for authorization of the five certification bodies are due July 30. A short turn-around time is expected.

Malec expressed concern about stage 2. The final rule has yet to be published. For eligible hospitals (EH) stage 2 begins October 1, 2013. The process is not going to meet the 18-month recommended preparation time. A hospital could easily miss stage 2 by a year and suffer the lost of financial incentives. He emphasized that he wanted CMS and ONC to understand the implications of the time frame. He suggested a delay in the schedule, a release of testing criteria with the final rule, or acceleration of the final rule. Bean indicated that she was in receipt of his statement. The testing criteria will be released with the final rule. The test procedures have their own timeline and process. Input must be obtained from various interest groups, making some time lag unavoidable. Staff is pushing as fast as possible. Relevant stakeholders are expected to step up and participate. Daniels reiterated that all comments to the NPRM must be reviewed and considered, which takes time. Malec repeated his concern about the grave financial implications for hospitals.

Baker referred to slide 8 and asked about modules evaluated both as a module and certified EHRs. Bean confirmed that they were counted twice.

Rishel asked about consultations with the public on testing procedures. Bean referred to web postings, workshops and webinars, saying that she welcomed suggestions for other venues. Tools and data for operability testing are not available at this time. They will be available for comment.

Jodi Daniel, Director, Office of Policy and Planning, reported that 110,000 health care providers became meaningful users by June 2012—20% of all U.S. eligible professionals. Regional Education Centers have assisted 133,000 primary care providers and 10,000 specialists. Her office is engaging in several new efforts. A long-term and post-acute care (LTPAC) roundtable was recently convened. A white paper is forthcoming. There are several state challenge grants and S&I efforts on LTPAC. A behavioral health roundtable will be convened later this month. A contractor is developing quality measures for behavioral health. Another project involves work with state prescription drug monitoring programs. These programs have data that are available in real time at the point of care and can be used in prescribing. Since ONC established a consumer program a year ago, 375 organizations have pledged to assist consumers. Her office is also engaged in a Blue Button Mashup Challenge with the Department of Veteran Affairs and a cancer focused use case for consumers.

Q and A

John Derr stated that LTPAC providers want to be included as volunteers in stage 3. Daniels invited members to indicate any interest in participating in the behavioral health roundtable.

7. Update on S&I Initiatives

Halamka reminded the group that this was the third consecutive attempt to review and discuss S&I initiatives. Doug Fridsma, ONC, began with slides that he had shown at the June meeting. He repeated that although ARRA funding is ending, the HITECH Act gave ONC the responsibility to support standards and certification criteria now and in the future. Therefore, S&I Framework activities will continue to support coordination around key initiatives. The HITSC will be involved with setting priorities. He noted the long list of standards development efforts in which the S&I Framework was and continues to be involved. He gave a snapshot of the portfolio: transitions of care, lab results interface, data segmentation for privacy, provider directory, certificate interoperability, Query Health, esMD, longitudinal coordination of care, public health reporting, laboratory orders interface and Health eDecisions. He spoke about the value of a public platform where the community can build consensus around a solution to a standards gap that must be addressed to support the exchange of health data. The ideal use of the S&I Framework is to build consensus around a standards solution when there are two or more standards that fail to address the needs of the community. He delineated the functions of the S&I Framework:

- Help identify standards gaps for health information exchange
- Provide a flexible process and dynamic tools that can support a community to create consensus around solutions for priority standards gap areas
- Evaluate the solutions emerging from the Framework and improve the Framework's processes and tools and refine the criteria for a successful S&I Framework initiative.
- Serve as a repository for standards products that have been developed using the S&I Framework platform.

He described current activities to develop the following:

- A standards gaps analysis for crucial health data exchange among primary health care stakeholders
- A governance process for the S&I Framework
- Initiative criteria to help determine whether an initiative would be appropriate for the S&I Framework
- Multiple tracks through which an initiative can achieve its goals
- A dynamic data dictionary that serves as a communication tool for users to understand the semantics behind the terms used within S&I Framework products. (Terms within the data dictionary would be reused and extended in future S&I initiatives)
- A standardized S&I Framework wiki workspace for the community that allows community members to easily participate in multiple initiatives without having to relearn new wiki page structures.

Fridsma concluded with a set of questions that he wished the HITSC to answer:

- What are the criteria for a successful S&I initiative?
- What does the HITSC see as its role within S&I coordination and priority setting?
- How does the HITSC wish to convey its prioritization of standards gap areas?
- What supportive information would the HITSC need to identify and prioritize standards gap areas?
- What kinds of flexibilities should be built into the Framework's initiative life cycle/process? How should a multi-track option for initiatives look like?
- What steps should be taken to properly evaluate the success of S&I Framework initiatives?

Discussion

The discussion was not organized around the questions. Halamka observed that with a known budget together with information on standards readiness, the HITSC could prioritize projects.

Nancy Orvis inquired about the current governance model for priorities. Fridsma said that priorities could be based on affordability or on expected impact. Funds should be used to leverage.

Malec talked about a process for portfolio management. He opined that the most successful projects to date were tied to policy goals and standards gaps. These were projects in which stakeholders had a vested interest. The criteria for measuring success should be policy need and tied to a standards gap.

Ferguson remarked that many countries have official standards bodies. ONC has not established itself as a national authority center, which would require coordination with other government bodies and private sector organizations. He suggested looking at other countries to determine the purpose of the S&I Framework. Fridsma responded that the National Library of Medicine contract and the FACAs may be steps in that direction. The Framework could serve as a necessary technical group. The work with the LTPAC group is not part of meaningful use but is nevertheless very relevant for accountable care organizations. ONC and the FACAs and the Framework could develop into a standards authority, but these three components could not constitute a complete authority. He went on to say that groups outside the United States recognize the potential for such a role for ONC.

McCallie declared his agreement with Malec. The Framework has been used as the place for nascent efforts.

Rishel said that the Framework had been good at getting standards ready for implementation. Deadlines help. Money is a driver; for example, the California Health Care Foundation has driven important changes through its funding strategy. Sustained operation is the measure of success, according to Rishel.

Kelly Hall said not to underestimate the significance of the S&L brand. Every electronic record function should have a corresponding patient facing system to allow contributions from patients. Current standards do not apply to patients. In the future patient facing systems should be designed in parallel with standards for providers. Fridsma acknowledged the difficulty of involving patients in standards development. Patients need to identify the problems. Dialogue will continue.

Baker observed that to date the HITSC had had little involvement in the establishment of priorities. She declared her agreement with Malec and McCallie. She suggested that each time the committee makes a recommendation it consider and comment on the implications for the Framework. She went on to suggest that the Framework staff incorporate the tracking of external, related projects. The HITSC, perhaps through a workgroup, could identify and prioritize external projects. Fridsma said that although coordination may not be explicit, the staff is watching other efforts.

Stan Huff indicated his agreement with others about the U.S. standards authority role. This is a transition period and a good time to deliberate on the role of such a body. Would it make standards, adopt standards or add to standards? Standards that have not been implemented in production should not be adopted.

Halamka noted that more time is required to discuss these questions.

Walker observed that attention is a resource. It will be difficult to do an adequate job of prioritization. Prioritization requires a representative, transparent body.

Eisenberg also supported a standards authority. But the need for standards is often deeper than the S&I Framework. Criteria for reliability, authority and feasibility should be set.

8. Public Comment
Gary Dickens, CentriHealth, commented that he was baffled by Fridsma's presentation. Because of his involvement with HITSP's vertical efforts, he had the same concern with the S&I approach. Repurposing is needed. He and others worked on an S&I simplification document regarding cross initiative commonalities. They went to great effort to analyze and catalog commonalities. The document is on the wiki. The work is continuing with the newer initiatives. There is now a repository, which is an opportunity on which to build. Why is this work not a centerpiece of how to proceed?

Shelly Shapiro, Pharmacy HIT Collaborative, talked about the work of her organization. It is involved in the pharmacy monitoring program. Pharmacists play an integral role in the care team. The collaborative prepared a roadmap for meaningful use and is participating in a joint project with HL7 on a medication action plan. The medication action plan includes a reconciled med list. As of January 2013, a med action plan will be required for part D.

SUMMARY OF ACTION ITEMS:

Action item #1: The summary of the June 2012 meeting was declared approved.

Meeting Materials:
Agenda

Summary of June 2012 meeting

Presentation slides